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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,423	11/28/2001	Kimberly A. Gillis	102729-12	6433

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,423	GILLIS ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 11-20, drawn to methods of assessing prostate cancer by detecting nucleic acids, classified in at least, for example, class 435, subclass 6.

II. Claims 1, 3-10, and 16, drawn to methods of assessing prostate cancer by detecting polypeptides, classified in at least, for example, class 435, subclass 7.1.

III. Claims 21 and 34, drawn to methods of assessing the efficacy of prostate cancer therapy *in vivo*, classified in at least, for example, class 424, subclass 9.2, and class 435, subclasses 6 and 7.1.

IV. Claims 22, 25-26, and 28, drawn to methods of assessing the effects of compounds on prostate cancer *in vitro* by detecting nucleic acids, classified in at least, for example, class 435, subclass 6.

V. Claims 22, 25, and 27-28, drawn to methods of assessing the effects of compounds on prostate cancer *in vitro* by detecting polypeptides, classified in at least, for example, class 435, subclass 7.1.

VI. Claims 23-24 and 31-33, drawn to antisense methods of treating cancer, classified in at least, for example, class 514, subclass 44.

VII. Claims 29-30, drawn to methods of assessing the effects of compounds on prostate cancer by determining protein activity, classified in at least, for example, class 435, subclass 183.

2. It is first noted that applicant has presented several claims that encompass both methods of detecting nucleic acids and methods of detecting proteins. Such claims are improper as nucleic acids and polypeptides are structurally and functionally distinct molecules. Nucleic acids are composed of nucleotides and function in, e.g., methods of hybridization, while proteins are composed of amino acids and function in, e.g., enzymatic methods or binding assays. Further, the method steps and reagents required to detect nucleic acids are separate and distinct from those required to detect proteins. Regarding claims 1, 3-7, 16, 22, 25, and 28, the claims have been included in multiple groups, and if any of these groups is elected, will be examined only to the extent that they are drawn to the elected invention. Group III includes only claims encompassing detection of both nucleic acids and proteins. As nucleic acids and proteins are improperly joined in the claims of Group III, **upon election of this group, applicants must further elect either nucleic acids or polypeptides**. See also *Ex parte Markush*, 1925 C.D. 126 and *In re Weber* 198 USPQ 328.

It is also noted that claim 19 as written depends from itself. As it appears the claim was intended to depend from the immediately preceding claim, claim 18 (which recites "cells"), claims 19-20 have been included in Group I.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V, VI and VII are patentably distinct methods having different objectives and/or requiring the use of different reagents in different process steps. Invention I requires steps of detecting the relative levels of nucleic acid expression (e.g., mRNA levels) in samples to achieve the objective of determining

whether a subject has prostate cancer. Invention II requires steps of detecting the relative levels of protein expression (using, e.g., antibodies) in samples to achieve the objective of determining whether a subject has prostate cancer. Invention III requires providing therapeutic agents to a subject to achieve the objective of assessing the efficacy of therapy in said subject. Invention IV requires steps of exposing samples to test compounds and detecting nucleic acid (e.g., mRNA) levels to achieve the objective of assessing efficacy or effects of the compounds. Invention V requires steps of exposing samples to test compounds and detecting polypeptide levels to achieve the objective of assessing efficacy or effects of the compounds. Invention VI requires administration of antisense oligonucleotides to achieve the objective of treating a subject. Invention VII requires steps of measuring protein activity to achieve the objective of identifying prostate cancer treatments. Accordingly, Inventions I-VII are patentably distinct from one another.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-VII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
March 22, 2003